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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/236,939	01/25/1999	PAUL J. GODOWSKI	P0854C1D4	9791

24510 7590 05/14/2003

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EXAMINER

ULM, JOHN D

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 05/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/236,939

Applicant(s)

Godowski

Examiner

John Ulm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 24, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-44 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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- 1) Claims 31 to 44 are pending in the instant application.
- 2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
- 3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 4) Claims 31 to 44 stand rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record in section 5 of Paper Number 11. Applicant continues to traverse this rejection on the premise that the claimed isolated nucleic acid has utility in the diagnosis and treatment of breast and liver cancer. Applicant has again failed to identify that specific portion of the instant specification which contains a specific assertion that the presence of a protein of the instant invention in breast or liver is diagnostic for cancer. Applicant identifies the text in lines 18 to 19 on page 97 of the instant specification as providing "an express asserted utility". The text referred to by Applicant states that "[t]hese results indicated that HPTK6 may play a role in cancer formation in certain cells, *e.g.*, human breast carcinoma cells". That statement does not constitute an assertion of a specific utility. At best, one of ordinary skill would accept that statement as a suggestion of a future avenue of research. It is a matter of law that an invention must have a specific and substantial practical utility "in currently available form" (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966)). This holding precludes the need for further

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experimentation for the purpose of identifying or establishing a specific utility for a claimed invention.

Applicant asserts that the examiner has failed "to address the Declaration of Dr. Paul Godowski, which was earlier submitted under 35 U.S.C. § 1.132". Applicant has failed to disclose the date upon which the purported declaration was filed and there appears to be no such declaration of record in the instant application.

Applicant's argument that the observed expression of a protein of the instant invention in a cell line origination from a liver cancer and a cell line originating from a breast cancer, but not in liver and breast, supports a *prima facie* utility for that protein as a cancer marker is not persuasive for those reasons of record and those reasons which follow. A cell line, by its very nature, differs from the cell type from which it was derived in at least three very fundamental aspects. First, the cell line was derived from a population of cancerous cells which, by definition, proliferate in a manner which distinguishes them from their tissue of origin. One would reasonably expect the oncogenic process leading to the transformation of a cell into a cancer cell would result in some alteration in the level and type of proteins expressed by that cell. Second, cell lines are derived from cancer cells through a process of immortalization. One of ordinary skill in the art of cell biology knows very well that the majority of primary cancer cells are not immortal and can not be immortalized. Those that are immortalized are often made so by extensive manipulative processes such as the introduction of agents like the Epstein-Barr Virus (EBV). One of ordinary skill would understand that any process leading to the immortalization of a cancer cell into cell line would

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also result in a significant alteration in the level and type of proteins expressed by that cell.

Whereas it is well known that the transformation of a "normal" cell into a cancer cell can result from an alteration of a single gene, the process of immortalization appears to be much more complex and poorly understood and probably has a more profound effect on the spectrum of proteins expressed by a cell. Finally, a "normal" cell *in vivo* grows in an environment which is substantially different from the *in vitro* environment of the cell line. One of ordinary skill would reasonably expect that simply changing the environment in which a cell is grown would result in a substantial alteration in the level and type of proteins expressed by that cell. Therefore, one of ordinary skill in art of molecular biology would not reasonably conclude that the observed expression of a protein of the instant invention in a cell line origination from a liver cancer and a cell line originating from a breast cancer, but not in liver and breast, supports a *prima facie* utility for that protein as a cancer marker.

5) Claims 31 to 44 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

6) Claims 31 to 33, 35 to 38 and 40 to 44 stand rejected under 35 U.S.C. 102(a) as being clearly anticipated by the Di Marco et al. publication (J. Biol. Chem. 268:24290-24295, 15 Nov. 1993) for those reasons of record.

7) Applicant's arguments filed 24 February of 2003 have been fully considered but they are not persuasive for those reasons given above.

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8) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JOHN ULM
PRIMARY EXAMINER
GROUP 1800